

CERTIFICATE OF ANALYSIS

Product Name: TUDCA (Tauroursodeoxycholic Acid) Capsules

Batch Number: TUDCA-CAP-20260122

Manufacturing Date: Jan 22, 2026

Expiry Date: Jan 21, 2028 (24 months shelf life)

Specification: 250mg per capsule

Packaging: 60 capsules per bottle (White HDPE bottle)

Report Date: Jan 28, 2026

1. Physical Characteristics

Test Parameter	Specifications	Results	Conclusion
Appearance	White or off-white powder filled in hard gelatin capsules	White powder, capsules intact and clean	Conforms
Odor	Characteristic odor	Complies	Conforms
Capsule Integrity	No leakage, no deformation	Intact, no deformation	Conforms
Average Net Weight	60 capsules \pm 3%	60 capsules, Net Wt. 15.2g	Conforms

2. Chemical Composition & Assay

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494 Forest Ave
Portland, ME 04101 USA

Test Parameter	Specifications	Conclusion
Identification (HPLC)	Retention time matches reference standard	Conforms
Assay (HPLC)	95.0% - 105.0% of label claim (237.5mg – 262.5mg per capsule)	Conforms
Loss on Drying	≤ 3.0%	Conforms
Residue on Ignition	≤ 0.5%	Conforms

3. Heavy Metals (ICP-MS)

Test Parameter	Specifications (USP <232>/<233>)	Results	Conclusion
Total Heavy Metals	≤ 10 ppm	< 10 ppm	Conforms
Arsenic (As)	≤ 1.0 ppm	< 0.5 ppm	Conforms
Lead (Pb)	≤ 1.0 ppm	< 0.5 ppm	Conforms
Cadmium (Cd)	≤ 0.5 ppm	< 0.2 ppm	Conforms
Mercury (Hg)	≤ 0.1 ppm	< 0.02 ppm	Conforms

4. Microbiological Analysis

Test Parameter	Specifications (USP <61>/<62>)	Results	Conclusion
Total Aerobic Count (TAC)	≤ 1,000 CFU/g	80 CFU/g	Conforms

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Test Parameter	Specifications (USP <61>/<62>)	Results	Conclusion
Total Yeast & Mold (TYM)	≤ 100 CFU/g	< 10 CFU/g	Conforms
Salmonella spp.	Negative / 25g	Negative	Conforms
E. coli	Negative / 10g	Negative	Conforms
Staphylococcus aureus	Negative / 10g	Negative	Conforms

5. Dissolution (For Capsules)

Test Parameter	Specifications (USP <711>)	Results	Conclusion
Dissolution (45 minutes)	Q ≥ 75%	89%	Conforms

6. Additional Information & Declarations

Status: This product meets Current Good Manufacturing Practices (cGMP) requirements for dietary supplements as per FDA regulations.

Allergen Statement: This product is **FREE** from the following allergens: Gluten, Wheat, Soy, Egg, Dairy, Shellfish, Peanuts, and Tree Nuts.

BSE/TSE Statement: This product is BSE/TSE free.

Irradiation: This product has NOT been irradiated.

GMO Status: This product is Non-GMO.

Storage: Store in a cool, dry place away from direct sunlight. Keep out of reach of children.

Shelf Life: 24 months from the date of manufacture when stored under recommended conditions.